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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/706,683	11/06/00	CHILDERS	W AM100151

EXAMINER

HM12/0615

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ART UNIT	PAPER NUMBER
1624	7

DATE MAILED: 06/15/01

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 1-38 is/are pending in the application.
Of the above, claim(s) 17-25, 31-38 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☑ Claim(s) 1-10, 12-16, 26-30 is/are rejected.
☑ Claim(s) 11 is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3, 4 & 5
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

PTOL-326 (Rev. 9/96)

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, drawn to compounds of formula (I), classified in class 544, subclasses 295, 393,400 based on the working examples.

II. Claims 16-36, drawn to multiple neurodegenerative diseases, classified in class 514, subclasses various.

III. Claims 37-38, drawn to treating pain, classified in class 514, subclasses various.

Inventions I and II-III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case more than one use exists as evidenced by the many being claimed as well as additional uses suggested by the art applied below. Additionally, the methods of use claimed would raise additional issues of patentability- at the very least 112 issues regarding the sole reliance on 5 HT1a receptor activity as a reasonable predictor of in vivo treatment for uses such as Alzheimer's Disease, ALS, retinal diseases. However, Mr. Mazzarese requested that one use, treating stroke, be examined. The examiner agreed this use would be examined on the merits. Claim(s) 16 in part as well as 26-30 read on said use.

During a telephone conversation with Mr.Mazzarese on 5/24/01 a provisional election was made with traverse to prosecute the invention of I, claims1-15. Affirmation of this election must be made by applicant in replying to this Office action. Claims 17-25,31-38 are withdrawn from

further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The disclosure is objected to because of the following informalities: The second US provisional application mentioned in the parent histroy on p.1 needs to be identified.

Appropriate correction is required.

Claims 5, 6 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1.The species in these claims appear to be incomplete as the tricyclic ring sytem is not mentioned in the name. Also see the typographical in "piperizinyl" .

2.The species of 13 is a carbamic acid ester.Such compounds are not embraced in main claim 1.

Claims 1,2,16,26-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled

in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

1. Scope of hetero rings permitted in R1,R2 and R3 is not adequately enabled as it reads on any array of monocyclic and polycyclic rings of varying hetero atoms as ring members for which specification does not teach the availability of the necessary starting materials nor the means by which they may be prepared for such a range of rings that can be attached at any ring position (via all C atoms as well as N in some cases). Furthermore compounds as diverse as the rings,ring systems embraced have not been shown as a class will have the minimum requisite activity needed to practice the invention. Compounds made and tested are not representative of such a scope but rather of generic claim 3. There is no reasonable basis for assuming that the myriad of compounds embraced by the claims will all share the same physiological properties since they are so structurally dissimilar as to be chemically non-equivalent and there is no basis in the prior art for assuming the same. Note US'552 applied below does not show such a scope at even one of the R locations. Note In re Surrey 151 USPQ 724 regarding sufficiency of disclosure for a Markush group. Also see MPEP 2164.03 for enablement requirements in cases directed to structure-sensitive arts such as the pharmaceutical art.

2. With regard to the elected use, treating stroke, said use is not rejected since the DeVry references provided teach a correlation for said use employing 5 HT1A agonists, which most of the limited compounds tested are. However use claims are rejected for the scope of compounds being claimed as in # 1 above.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10,12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abou-Gharbia (US'552) in view of Cliffe (US '278) . The primary reference teaches similar compounds to that claimed herein for uses associated with binding to the 5 HT1A serotonin receptor site. These include the uses depression,anxiety. Also dislcosed is central cholinergic activity for treatment of dementias of the Alzheimer's type. Closest compounds in col.2 (2nd and 3rd species) differ only in lacking instant Y-R1 group.

Cliffe teaches for similar compounds and uses associated with serotonin antagonism the placement of benzyl groups (including substituted benzyl) on alkyl carbon adjacent to nitrogen of carboxamide group. See definition of R3 and X which includes -NR4COR6. Thus it would have been obvious to one skilled in the art at the time the invention was made to replace a hydrogen in "alpha" carbon of Abou-Gharbia's compounds with benzyl groups taught by Cliffe and in so doing obtain instant compounds with the expectation that they too would be useful as serotonin antagonists in view of the equivalency teaching outlined above.

Claim 11 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any

intervening claims. The substituent corresponding to Y-R1 is not taught or suggested by the closest art of record applied above.

Any inquiry concerning this communication should be directed to Emily Bernhardt at telephone number (703) 308-4714.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

E Bernhardt

EMILY BERNHARDT
PRIMARY EXAMINER